DEC 15 2011

510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is K102456

Submitter Information (21 CFR 807.92(a)(1))

Submitter:

Takara Belmont USA, Inc.

Belmont Equipment Division

101 Belmont Drive

Somerset, NJ 08873-1204

Contact Person: Robert Schiff
Telephone: 973-227-1830

Summary Date: August 20, 2010

Device Name/Classification (21 CFR 807.92(a)(2))

Proprietary Name:	Intraoral BelSensor GOLD
Common/Usual Name:	Digital X-ray Sensor
Classification Name:	Class II Extraoral source x-ray system, per 21 CFR § 872.1800
Classification Code:	MUH

Substantially Equivalent/Predicate Devices (21 CFR 807.92(a)(3))

Predicate Device 1: Dexis Sensor (K090458)

Device Description (21 CFR 807.92(a)(4))

The BelSensor GOLD is an indirect converting x-ray detector that converts incident x-rays by a scintilator into visable light, which is coupled optically to a light detection imager based on CMOS technology. Incident x-rays are automatically detected to generate digital images for dental intra-oral applications.

The BelSensor GOLD supports USB 2.0 connectivity to personal computer.

Device Intended Use (21 CFR 807.92(a)(5))

The BelSensor GOLD is a USB-driven digital sensor which is intended to acquire dental intra-oral radiology images. The BelSensor GOLD shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intra-oral radiographs. The BelSensor GOLD can be used either in combination with special positioning devices to facilitate positioning and alignment with the x-ray beam or it may also be positioned by hand with the assistance of a patient.

Technological Characteristics (21 CFR 807.92(a)(6))

Comparison of the Principal Characteristics of the Belmont BelSensor and the DEXIS Sensor

Descriptive Information	Belmont BelSensor GOLD	Dexis Sensor (K090458)
Indication for Use	The BelSensor GOLD is a USB-driven digital sensor which is intended to acquire dental intra-oral radiology images. The BelSensor GOLD shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intra-oral radiographs. The BelSensor GOLD can be used either in combination with special positioning devices to facilitate positioning and alignment with the x-ray beam or it may also be positioned by hand with the assistance of a patient.	The DEXIS sensor is a USB-driven digital sensor which is intended to acquire dental intra-oral radiology images. The DEXIS sensor shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intra-oral radiographs. The DEXIS sensor can be used either in combination with special positioning devices to facilitate positioning and alignment with the x-ray beam or it may also be positioned by hand with the assistance of a patient.
Number of Sensors	2	1
Sensor Size (mm)	30 x 20 36 x 26	30 x 39
Technology	CMOS	CMOS
Interface with PC	USB	USB
Dynamic Range	15,000:1	16,384:1
Sensor Cable Length (m)	3	2.8

Safety, EMC, Biocompatability and Performance Data

Electrical, mechanical, environmental safety and performance testing according to IEC 60601-1 (2005) was performed, and EMC testing was conducted in accordance with standard IEC 60601-1: 1988 + A1: 1991 + A2:1995, IEC 60601-1:2005 (without 60601-1-6), EN 60601-1: 2006, (without 60601-1-6), EN 60601-1-2: 2007.

Biocompatability for the cable and housing material was conducted under USP testing guidelines. Detailed information can be found in Attachment 7.

Conclusion: The Belmont BelSensor GOLD is substantially equivalent to other legally marketed devices in the United States. The Belmont BelSensor GOLD is substantially equivalent in intended use and technical characteristics to the DEXIS Sensor marketed by Sybron Dental Specialties, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Takara Belmont USA, Inc.
% Robert Schiff, Ph.D., RAC, CQA, FRAPS
President and CEO
Schiff & Company
1129 Bloomfield Avenue
WEST CALDWELL NJ 07006

DEC 15 2011

Re: K102456
Trade/Device Name: BelSensor GOLD
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: November 10, 2011
Received: November 14, 2011

Dear Dr. Schiff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~Not assigned yet~~ K102456
Device Name: BelSensor GOLD

Indications for Use: The BelSensor GOLD is a USB-driven digital sensor which is intended to acquire dental intra-oral radiology images. The BelSensor GOLD shall be operated by healthcare professionals, who are educated and competent to perform the acquisition of dental intra-oral radiographs. The BelSensor GOLD can be used either in combination with special positioning devices to facilitate positioning and alignment with the x-ray beam or it may also be positioned by hand with the assistance of a patient.

Prescription Use X **Over-The-Counter Use**_____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102456